Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0566728	08/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Philip C Bosch Md	651 E Pennsylvania Ave Ste 201, Escondido, CA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control (QC) records and interview with the laboratory director, it was determined that the laboratory failed to routinely have control procedures that monitor the accuracy and precision of the complete analytic process, and failed to monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. The findings included: a. The laboratory is a physician office laboratory (POL), specialized in urology. b. The laboratory performed direct susceptibility urine culture for sensitivity to the following antibiotics, Ampicilline, Ciprofloxacin, Gentamycin, Nitrofurantoin, Tetracyclin, and SXT for a positive growth based on colony count for urine culture in blood agar (BA) media. c. Interview with the laboratory director for the direct urine sensitivity testing quality control records, the laboratory failed to maintain proper quality control activity records. d. For direct susceptibility testing, the laboratory must establish its own size ranges for zones of inhibition with QC organisms.

D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory's direct susceptibility for urine culture patient test result reports and its worksheets, and interview with the laboratory director and the personnel, it was determined that the laboratory failed to effectively monitor and quality assess to ensure the accuracy of the urine culture testing and the results transcribed from worksheets to NexGen, an electronic medical record (EMR) system. The findings included: a. The laboratory is a physician office laboratory (POL), specialized in urology. b. The laboratory performed direct susceptibility urine culture for sensitivity to the following antibiotics, Ampicilline, Ciprofloxacin, Gentamycin, Nitrofurantoin, Tetracyclin, and SXT for a positive growth based on colony count for urine culture in blood agar (BA) media. c. Review of 6 patient final test reports printed out from EMR and its worksheets, Patient Acct#0347 reported on 08/08/2019 indicated a missing disk of Gentamycin in the process of this patient sample testing. d. The laboratory personnel mistakenly entered a 100 colony count for a 80 colony count from the worksheet to EMR for the patient Acct# 1912 reported date of 07/25/2019. e. The laboratory failed to quality assess and document for the activities and failed to take corrective actions.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records, and patient urine direct susceptibility culture test result reports with its worksheets, and interview with the laboratory director and the laboratory personnel, it was determined that the laboratory director failed to ensure that the quality control programs and quality assessments were established and maintained to ensure the accuracy of the testing results and reports, and to provide quality of laboratory services and document all laboratory testing activities. The findings included: a. The laboratory is a physician office laboratory (POL), specialized in urology. b. The laboratory performed direct urine culture for sensitivity to the following antibiotics, Ampicilline, Ciprofloxacin, Gentamycin, Nitrofurantoin, Tetracyclin, and SXT for a positive growth based on colony count for urine culture in blood agar (BA) media. c. The laboratory must properly perform quality control for its direct susceptibility urine culture according to its written policies and procedures, and assess the accuracy of the patient testing result reports, see D-5441 and D-5891.